Message

From: Faeth, Lisa [Faeth.Lisa@epa.gov]
Sent: 9/1/2016 3:58:36 PM
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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

EPA Posts Confidentiality Guidance for Chemical Companies

Posted: Sep 1, 2016, 9:52 AM EDT

By Pat Rizzuto

The Environmental Protection Agency has posted online guidance for chemical manufacturers making confidential business information claims under the amended U.S. chemicals law.

The EPA's newly posted guidance summarizes the law's new requirements; provides text, which companies making paper submissions must provide; describes the agency's plans to review claims; and includes answers to questions that may arise.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. Law 114-182), which amended the Toxic Substances Control Act as of June 22, requires chemical manufacturers to substantiate their assertions that certain information they submit to the EPA must be protected from public disclosure. The EPA must, with limited exceptions, review all confidential business information claims that manufacturers assert for chemical identity, and the law requires the agency to review a representative sample, meaning at least 25 percent, of other confidential business information claims.

Industry Group Calls for Tougher Paint Stripper Labeling

Snapshot

• Consumer Product Safety Commission will accept comments on a tougher warning label

• The action would affect products made with methylene chloride

• Halogenated Solvents Industry Alliance petitioned for the change

By Sam Pearson and Pat Rizzuto

Aug. 31 — The U.S. Consumer Product Safety Commission is seeking public comment on an industry request to make tougher warning label language for some paint strippers.

The Halogenated Solvents Industry Alliance Inc. petitioned the commission Aug. 17 and asked it to require companies making household products with methylene chloride to add a warning to their labels about the risks the chemical may pose following short, high exposures, also called "acute" exposures.

The commission acknowledged the petition in a notice scheduled to be published in the Federal Register Sept. 1. The commission is accepting public comments on the trade association's request through Nov. 1.

The commission's current requirement, issued in a 1987 policy statement under the Federal Hazardous Substances Act, is that household products containing methylene chloride carry a warning about risks from chronic exposures—but not acute ones. Methylene chloride is also known as dichloromethane or DCM.

The petition said 14 workers have died following use of DCM-based paint strippers while refinishing bathtubs. The Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health also published a hazard alert after one worker's death, the petition said.

Consumers are also at risk when they perform this work, the petition said.

"Many stripping products contain substantial amounts of methylene chloride," the petition said. "Use of these chemicals in bathrooms, which are often small, enclosed spaces with little or no ventilation, can be very dangerous."

Dozens of Products Listed in National Database

More than 40 auto, home maintenance and other consumer products are listed as containing methylene chloride, according to the National Library of Medicine's Household Products Database. These products include concentrations of the solvent ranging from 5 percent to 100 percent, the database said.

Manufacturers of these products include the Radiator Specialty Co., Savogran Co., and W. M. Barr & Co.

Faye Graul, the alliance's executive director, told Bloomberg BNA Aug. 31 it was important that the petition be adopted to ensure all companies use labels that incorporate the latest knowledge.

Graul said commission staff agreed in meetings that the change was necessary but declined to present the matter to the full commission for approval because the panel is already working on other issues.

Alliance in Touch With Manufacturers

Graul said the alliance has been in touch with "at least 95 percent of the community" that manufactures the products but wants to see the changes made official commission policy.

"We just want to make sure that no one uses the product and is harmed," Graul said.

Separately, the Environmental Protection Agency has said it plans to propose a rule by the end of 2016 to restrict the use of methylene chloride in paint strippers.

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and Sam Pearson in Washington at spearson@bna.com
To contact the editor responsible for this story: Larry Pearl at lpearl@bna.com

For More Information

The Halogenated Solvents Industry Alliance petition is available at http://src.bna.com/icO. *The Federal Register notice is available at: http://src.bna.com/icA*.

Liver Effects Central to Draft EPA Review of Fuel Oxygenate

Snapshot

•A draft EPA risk assessment of ethyl tertiary butyl ether's health effects to be published Sept. 1

•Questions on chemical's liver effects to be discussed at Oct. 26 EPA meeting

By Pat Rizzuto

Aug. 31 — The Environmental Protection Agency is scheduled to release Sept. 1 a draft assessment of a fuel oxygenate called ethyl tertiary butyl ether, according to a prepublication Federal Register notice.

Ethyl tertiary butyl ether is used as a fuel additive for gasoline to increase octane rating and has been used to meet air pollution reduction goals under the Clean Air Act, according to information from the EPA. The use of oxygenates such as ETBE in reformulated gasoline in the U.S. was effectively eliminated in 2006, but use and production has continued to increase gasoline's octane rating, the EPA said.

The assessment, conducted under EPA's Integrated Risk Information System (IRIS), will examine the human health hazards of ETBE and the doses at which those hazards could manifest. Final IRIS assessments, or "toxicological reviews,"

are used throughout the agency, U.S. states and regulators in other parts of the world as part of the information they use to assess the risks a chemical poses at a particular site or when used in particular ways. The resulting risk assessments contribute to decisions on whether an industrial activity, hazardous waste site, or other situation needs to be regulated.

Lyondell Chemical Co. and one other company, which claimed its name to be confidential business information, were the two U.S. manufacturers of ETBE in 2011, the most recent year for which U.S. production data is available from the EPA. The agency withheld ETBE's national production volume information to protect proprietary information.

European companies that have registered ETBE include BP p.l.c., Exxon Mobil Corp. SABIC Petrochemicals and Shell. The oxygenate is registered as having an annual European production volume of 1 million to 10 million metric tons.

2009 Draft Assessment Put on Hold

The EPA's IRIS program has not issued a final assessment of ETBE previously, although the agency published a draft assessment in 2009. That draft assessment proposed to classify ETBE as having "suggestive evidence of carcinogenic potential." It also proposed a reference concentration (RfC) of 0.006 milligrams per cubic meter of air. RfCs are the agency's estimate of a continuous does that people could inhale over their lifetime without expectation of harm.

The ETBE assessment, however, was among four IRIS chemical evaluations the agency placed on hold after the U.S. National Toxicology Program and an Italian research organization called the Ramazzini Institute reached divergent opinions on cancer data the institute had generated.

In a 2013 presentation, the IRIS program said it was again reviewing ETBE. It was examining kidney, liver, reproductive, developmental and carcinogenic effects, among other potential health problems.

Following that meeting, the Petroleum Industry Technology and Research Institute Inc. of Japan sent the EPA a letter arguing that ETBE did not meet the criteria for an IRIS assessment.

"Current uses of ETBE in the United States are virtually non-existent. Manufacture of ETBE in the U.S. is predominately for export only," the Japanese trade association wrote.

Questions about the effects ethyl tertiary butyl ether may have on the liver are among the issues the EPA also will discuss at an Oct. 26 public science meeting.

To contact the reporter on this story: Pat Rizzuto in Washington at prizzuto@bna.com

To contact the editor responsible for this story: Larry Pearl at lpearl@bna.com

For More Information

A prepublication copy of EPA's Federal Register notice announcing the ETBE assessment is available at http://src.bna.com/ib3.

INSIDEEPA.COM ARTICLES

EPA Urged To Clarify Plan For Prioritizing Chemical Reviews Under TSCA

Chemical industry groups are urging EPA to clarify its plans for implementing a mandate under the revised Toxic Substances Control Act (TSCA) for designating substances as either high or low priority for review, including how it will apply to new chemicals and what the agency will do when there is inadequate safety data for a substance.

Justices Urged To Reverse Ruling Limiting Acting EPA Official's Decisions

The Department of Justice (DOJ) and its allies are urging the Supreme Court to reverse an appellate ruling that sets a strict test for when nominees for top EPA and other agency positions can serve in the same role in an acting capacity, a decision seen as undermining decisions by officials such as Acting Deputy EPA Administrator Stan Meiburg.

Industries, Advocates Query EPA's Plan For TSCA Review Rule Definitions

Groups representing major industrial sectors and environmentalists are querying how EPA plans to define key terms for its pending rule under the revised Toxic Substances Control Act (TSCA) to prioritize chemicals for risk assessment, including "susceptible subpopulations" and how to satisfy a statutory mandate for scientific integrity.

Environmentalists Fight Chemical Industry Bid To Limit TSCA Fees' Scope

Environmentalists are fighting some chemical sector officials' suggestion that EPA limit the scope of fees the agency would impose for industry-requested chemical risk evaluations under the revised Toxic Substances Control Act (TSCA), saying companies should pay 50 to 100 percent of the costs regardless of the breadth of the assessment.

New EPA Advisory Panel Praises Solvent Review But Urges Biomarker Use

A new EPA advisory panel dedicated to peer reviewing risk assessments from the agency's toxics office has issued its first review, generally praising EPA's draft analysis of a common solvent but urging consideration of biomarker data that suggests widespread exposure to the chemical and could increase estimates of bystander exposures.

GREENWIRE ARTICLES

Contamination forces housing project residents to relocate

Residents at the West Calumet public housing project in East Chicago, Ind., are being forced to relocate due to lead contamination.

U.S. EPA has found elevated levels of the heavy metal in soil around the building complex. The agency first detected "hot spots" of lead 10 years ago, but it was not until May 2016 that EPA declared lead was at emergency levels.

CHEMICAL WATCH ARTICLES

Sweden 'prepared' for UN's 2030 sustainability goals

1 September 2016 / Green chemistry, Sustainable chemistry, Sweden

Sweden's system of environmental objectives is "well placed" to implement the UN's goals for its 2030 agenda of sustainable development, the country's chemicals agency Kemi says.

In a report to the government, Kemi says preventive chemical management is a "prerequisite" for sustainable development and will help contribute to the achievement of many agenda 2030 objectives.

The agency proposes the following strategic measures to achieve the 2030 agenda:

- continue to work for an "ambitious" EU strategy for a non-toxic environment by 2018;
- strengthen knowledge within higher education about the health and environmental aspects of the use of chemicals in society;
- continue to work for a new global goal for the sound management of chemicals after 2020; and
- work for a global framework convention for the management of chemicals that are of global concern.

Further Information:

- Kemi's report (summary in English)

Cellular dose crucial for comparing nanoparticle studies, says JRC

Factor is often overlooked in literature

1 September 2016 / Alternative approaches to testing, Europe, Nanomaterials, Risk assessment

Calculating the fraction of nanoparticles that actually come into contact with cells (cellular dose), during an *in vitro* study, is crucial for determining the dose response for risk assessment, according to the European Commission's Joint Research Centre (JRC).

With the constant increase in nanomaterials in consumer products, there is a need for robust, standardised and reliable *in vitro* test methods for toxicity screening, say JRC researchers. However, they acknowledge that developing these for nanomaterial hazard assessment is "not straightforward".

The cellular dose is often overlooked in the literature, making it difficult to compare datasets from different studies, they say. Estimating this is "not trivial", depending on the transport of nanoparticles and on their affinity for cell membranes, as well as the capacity of cells to take up the particles.

A JRC team, led by Pascal Colpo, studied gold nanoparticles to relate their physico-chemical properties to deposition on a layer of cells *in vitro*. The particles are used in many model systems because of their biocompatibility, stability and inert nature.

First, they characterised nanoparticles in cell medium to determine the diameter and apparent mass density of the nanoparticle–protein complexes that inevitably form. Then, using UV-visible absorbance measurements to study kinetics, the researchers confirmed that the fraction of deposited nanoparticles differs greatly from the initial concentration.

The fraction deposited is highly dependent on nanoparticle size and apparent density, with smaller particles leading to less deposition.

"This study shows that an accurate characterisation is needed, and suitable experimental conditions, such as initial concentration of nanoparticles and liquid height in the wells, has to be considered since they strongly influence the cellular dose and the nature of interactions of nanoparticles with cells," write the researchers in *Particle and Fibre Toxicology*.

The team hopes that its systematic studies will "help to develop robust, standardised and reliable *in vitro* assays for nanomaterial toxicity screening".

Note: Your access to this subscriber-only article is through a corporate subscription

Dr Emma Davies

Reporter

Further Information:

- Journal article (open access)

Swedish agency finds banned chemicals in plastic goods

1 September 2016 / Enforcement, Halocarbons, Phthalates, Sweden, Textiles & apparel

A spot check by the Swedish Chemicals Agency (Kemi) of plastic goods has found that almost 10% contained prohibited chemicals.

The agency examined 160 plastic products from 52 companies for:

- phthalates (plasticisers);
- short-chain chlorinated paraffins (plasticisers and flame retardants);
- lead;
- cadmium; and
- dimethylformamide/methylacetamide.

The articles checked were items that can be found around the home, including bathroom products, garden equipment, working gloves, bags and sports equipment. Most were made of soft plastic.

The most common substances found were short-chain chlorinated paraffins used as plasticisers and flame retardants, the agency report says.

And the results show a lot of articles – mostly those made of PVC – contain substances with hazardous properties.

In its investigation Kemi found:

- 14 articles contained restricted substances in levels above their limit values;
- 24 contained substances on the REACH candidate list at levels above 0.1% by weight;
- 44 had low levels – below the limit value – of restricted substances, or hazardous chemicals that were not restricted in the particular kind of article; and
- 78 articles in which none of the substances were found.

When informed of the agency's analyses, some companies voluntarily stopped selling the goods. In two cases Kemi imposed a ban on the articles. A further 20 companies were reported to the environmental prosecutor.

"The levels of hazardous substances are low in most of the goods, but overall it is about large amounts, which will eventually become waste. It is important that companies set clear chemical requirements for their suppliers," says Marcus Hagberg, an inspector at the agency.

Kemi previously held meetings with industry about softeners in plastics and rubber, with discussions on using phthalates.

Related Articles

- Sweden to hold meetings on plastics and rubber softeners

Further Information:

- Kemi report (summary in English)

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1 September 2016 / Enforcement, Halocarbons, Phthalates, Sweden, Textiles & apparel

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Related Articles

- Sweden to hold meetings on plastics and rubber softeners

Further Information:

- Kemi report (summary in English)

Reformed TSCA to reduce use of 'unreliable' animal testing

But alternate approaches raise validation concerns

1 September 2016 / Lautenberg, Test methods, United States

Provisions to reduce animal testing under the reformed Toxic Substances Control Act (TSCA) will ensure the collection of better information, say supporters.

Toxicology expert at NGO Physicians Committee for Responsible Medicine, Kristie Sullivan, said that the animal testing provisions will ensure "strong" protection of human health and the environment. These were broadly supported by NGOs, industry groups and members of Congress alike during development of the Lautenberg Chemical Safety Act (LCSA), which amends TSCA.

"We lack information on many chemicals and how they affect a diverse human population, because we [have relied] too heavily on slow, unreliable and expensive animal tests," added Dr Sullivan. The updated law's approach will allow the EPA "to collect better information more quickly than current tests [under old TSCA] allow."

Under the reformed TSCA, the EPA is directed to "reduce and replace the use of vertebrate animals in the testing of chemical substances or mixtures. It must do this to the "extent practicable, scientifically justified and consistent with the policies" of the law.

The LCSA also requires the agency to develop, by June 2018, a strategic plan to reduce animal testing. And it is required to provide a subsequent report to Congress every five years on its progress in implementing this, and on its goals to further reduce the testing.

Daniel Rosenberg, a senior attorney at the Natural Resources Defense Council (NRDC), says that the LCSA promotes non-vertebrate testing through the "development of a strategic plan". This includes "factors" that the EPA must consider, but is not required to act on.

The law says the agency should first take into account, as appropriate and to the extent practicable and scientifically justified, any reasonably available data, or other methods that could be used, before animal testing is required, he says.

Validation

But some consumer advocates have concerns about the validation of alternative methods. Mr Rosenberg says that despite the positive aspects of moving away from animal testing, "there's a lot of concern that the [alternative] methods could be brought into use, before they have been sufficiently validated."

He adds that using alternative methods could result in chemicals being wrongly concluded as safe – either because of lack of toxicity or insufficient proof of exposure – that "aren't really borne out by the methods being used".

Christina Franz, senior director of regulatory and technical affairs at the American Chemistry Council, says that improvements in tools and alternative methods are "ongoing". The best of these, she adds, should be integrated as they become available.

This approach "is entirely consistent with the statutory new requirements to use best available science and weight of the evidence in the risk evaluation process", she says. "Chemical manufacturers and animal rights activists share a desire to reduce testing on animals," she adds.

Mr Rosenberg acknowledges that the EPA, together with the chemical industry and animal rights groups, have been "very supportive" of efforts to transition to alternate test methods, including high-throughput screening.

But some members of the environmental health community, he says, see both the promise and the need to "go slowly and carefully" in drawing conclusions from these methods. This is because they will have significant consequences for the environment and public health, as well as state authorities.

LCSA requirements

The LCSA requires the EPA to take into consideration toxicity information, computational toxicity and high-throughput screening methods, prior to performing animal tests under TSCA.

The EPA is also directed to minimise animal testing, by "encouraging and facilitating":

- the use of alternative test methods that provide information "of equivalent, or better, scientific quality and relevance";
- the grouping of similar substances into categories to reduce testing volume; and
- the formation of industry consortia to do joint testing.

Kelly Franklin

Editor, North America

Related Articles

- New TSCA will help EPA meet testing needs

Taiwan loading data on new substances to public platform

But NGOs say move favours confidentiality over disclosure

1 September 2016 / Confidentiality & right-to-know, Taiwan, TCSCA

Taiwan's EPA has begun loading new substances information onto the online public platform it launched last December.

Chen Shu-lin, deputy director of the EPA's Department of Sanitation and Toxic Substance Management, told *Chemical Watch*: "The site contains registrations provided by companies that have not applied [for confidentiality]. It is designed to be used mainly by potential registrants looking to confirm whether new chemical substances have already been registered."

The information is only available in Chinese, but Ms Chen says bilingual listing will be introduced "by the end of this week".

But local environmental organisations have said the platform favours confidentiality over disclosure.

At present, there are 151 substances listed, including 138 for small volume and 13 for small volume transitional substances. This is despite companies completing nearly 1,159 new substance registrations.

According to the EPA, this includes 1,141 small volume registrations, 13 simplified registrations and five standard registrations.

The next scheduled major update of the database is slated for December, when the number of substances will increase sharply, as it will list those for which full or partial CBI has not been approved.

But director of the NGO Citizen of the Earth, Lee Han-lin, says: "It is difficult to see how the principle of 'public disclosure' [cited] in Article 41 of the TCSCA is being honoured, if only 10% of registered new chemicals are being disclosed."

Most registrants applying for confidentiality

Ms Chen acknowledged that the gap was primarily due to requests for confidentiality under Article 41 of the Toxic Chemical Substances Control Act (TCSCA).

A total of 612 registrants (53%) have asked for full or partial confidentiality. Of these the EPA has rejected only 57.

Dennis Engbarth in Taipei

More information on CW+AsiaHub

Related Articles

- EPA begins loading new substances data on public platform

Bisphenol AF linked to impaired reproductive function

1 September 2016 / Bisphenols, Global, Toxicology

Developing male rats exposed to bisphenol AF (BPAF) via their mothers bioaccumulate the compound and have higher testis testosterone levels, according to a Chinese study. This exposure can impair reproductive function, the authors say.

BPAF is a fluorinated derivative of bisphenol A. It is used as a crosslinker in fluoroelastomers and as a monomer for speciality polymers. It has oestrogenic properties, but its effects on development are little understood.

The authors, from Beijing's Chinese Academy of Sciences, fed gestating and lactating rats the compound. They found the offspring were exposed via cord blood and milk.

In male offspring BPAF accumulated in the testis and increased testosterone levels.

The authors found that 279 genes were differentially expressed and gene expression between two adjacent germ cell types was disrupted.

The study is published in the journal *Chemosphere.*

Related Articles

- US scientists examine endocrine activities of BPA, BPAF

Further Information:

- Abstract

Danish EPA surveys children's products for allergenic substances

1 September 2016 / Alternatives assessment & substitution, Children's products, Denmark, Personal care, Product testing, Sensitisers

The Danish EPA has investigated the presence of allergenic substances in toys and cosmetic products that are in prolonged contact with children's skin.

It also looked into whether corresponding products without such substances can be found.

The EPA tested 157 cosmetic products for 191 potentially allergenic substances. At the same time it questioned the Danish toy sector on use of the substances.

The research found that fragrances could constitute the biggest problem with regards to allergy.

However, with the exception of hair sprays and perfumes, it says it is possible to find products without potentially allergenic substances for nearly all of the types of article examined.

In June 2014 a Danish survey revealed that more than one in three toy manufacturers, importers, or dealers in Denmark did not know enough about the rules governing the use of chemicals in their products.

And in July 2013 the country began a three-year programme to inspect container ships carrying products for children to verify that products entering the country comply with national and EU chemical legislation.

Related Articles

- Danish survey reveals high level of toy safety ignorance
- Denmark to tighten chemical control over products for children

Further Information:

- EPA report

China consults on alternative test method for cosmetics

Use of OECD-accepted TER method proposed

31 August 2016 / Alternative approaches to testing, China, Personal care

China's National Institutes for Food and Drug Control (NIFDC) are consulting on a proposal to use an internationally recognised test standard for cosmetic ingredients. The consultation ends on 10 September.

According to an industry source, if the proposal is accepted, it would be the first alternative method to be used in China, except for some *in vitro* tests used for genotoxicity.

NGO Humane Society International (HSI) says this is part of ongoing efforts to align the country's regulatory frameworks with those of key international trading partners.

China currently requires pre-market eye and skin testing on animals for all imported and special-use cosmetics. This includes cosmetic ingredients, even when existing data for internationally recognised non-animal test methods is available.

The OECD-accepted alternative method, called transcutaneous electrical resistance (TER), uses the skin discs from euthanised rats to test a substance for up to 24 hours. The discs are then washed and the TER of the skin is measured. The skin from one rat may be used to test up to five chemicals, with no live animal testing required.

Luo Feiya at the NIFDC told *Chemical Watch* that the CFDA asked the institutes to investigate whether the method would perform well enough to replace animal testing.

She adds that they hope to recommend that the method be drawn up into a standard, but this decision will be made by the CFDA.

But director of science and regulatory affairs at Cruelty Free International, Dr Katy Taylor, points out that, while this is promising news, it is "unfortunate this test (involving dead rats) has been chosen, rather than the internationally accepted, humane and human-relevant method that utilises human skin".

More information on CW+AsiaHub

Charlotte Niemiec

Asia editor

Related Articles

- Food and drug institutes propose alternative test method for cosmetics

Further Information:

- NIFDC proposal

- HSI press release

Congressman to propose expanded FDA authority over cosmetics

31 August 2016 / Personal care, United States

Congressman Frank Pallone, Jr (D–New Jersey) intends to introduce a bill that would provide the FDA with additional authority to regulate cosmetic products.

Ranking member on the House Energy and Commerce Committee, Mr Pallone has also requested a full committee hearing on the current regulatory framework for cosmetics.

In a letter to Chairman Fred Upton (R–Michigan), he flagged up several concerns with the FDA's current authorities under the Food, Drug and Cosmetic (FD&C) Act . These include that:

- the agency does not verify the safety of cosmetics before they are offered for sale;
- individual companies are responsible for testing the safety of their products and are not required to share these findings with the FDA;
- cosmetics manufacturers have no obligation to inform the agency of adverse effects reported by consumers either; and
- the agency is not able to issue a mandatory recall.

The congressman intends to introduce a bill this autumn that will build on his 2012 Cosmetics Safety Enhancement Act (HR 4262) to address these concerns.

The Personal Care Products Safety Act (S 1014) was introduced in the Senate, last year, with similar aims. But the measure has remained stalled in committee.

A coalition of nearly 30 companies and organisations – including Unilever, Johnson & Johnson and the Environmental Working Group – recently urged leaders of the Senate committee of jurisdiction to move the bill forward.

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Further Information:

- Press release
- Pallone letter
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